UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,656	11/28/2006	Rudi Mueller-Walz	28069-625N01US	2553

35437 7590 03/12/2010

MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER	
KENNEDY, NICOLETTA	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
03/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,656	MUELLER-WALZ ET AL.	
	Examiner	Art Unit	
	Nicoletta Kennedy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 12-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 12-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-7 and 12-23 are currently pending.

Priority

This application, filed April 14, 2006, is a national stage entry of PCT/IB04/03804 filed November 11, 2004, and claims foreign priority to United Kingdom application 03266327, filed November 14, 2003. The International Bureau has provided a certified copy of the United Kingdom application.

Election/Restrictions

1. Applicant's election of Group I, claims 1-7 and 12-23 in the reply filed on August 5, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Applicants have canceled the non-elected claims. Claims 1-7 and 12-23 are currently under examination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-7, 12, 14 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth et al. (WO 01/78693) (pub. Oct. 25, 2001) (provided by Applicants).

Regarding claim 1, Staniforth et al. teach a powdery formulation comprising active ingredients, coarse carrier particles and from 0.02 to 1.5% by weight of magnesium steatrate in the final formulation (p. 5-6; p. 14, lines 12-17). The magnesium stearate particles partially coat the surface of the excipient particles or the coarse carrier particles (p. 6, lines 19-21). The surface coverage of the coarse carrier particles can

vary depending on the amount and particle size of the fine fraction and is at least 5% (p. 11, lines 3-8). However, Staniforth et al. do not teach specific values for the amount of magnesium stearate by weight when the surface coverage of the carrier is less than 10%. The broad teachings of Staniforth et al. in view of MPEP 2144.05 cure this deficiency.

MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, with regard to the surface coverage, Staniforth et al. teach surface coverage of the carrier of at least 5%. This range of at least 5% overlaps the claimed range of less than 10% and therefore renders the claimed range prima facie obvious. With regard to the amount of magnesium stearate, the claimed range of at least 0.5% by weight of the formulation overlaps the range of 0.02 to 1.5% taught by the prior art and is therefore prima facie obvious.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Staniforth et al. to use an amount of magnesium stearate and to provide surface coverage of the carrier particles consistent with the instantly claimed ranges. One would have been motivated to do so because Staniforth et al. teach the use of magnesium stearate and providing surface coverage of the carrier particles within these ranges.

Regarding claim 2, Staniforth et al. teach that the surface coverage of the coarse carrier particles can vary depending on the amount and particle size of the fine fraction

and is at least 5% (p. 11, lines 3-8). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, with regard to the surface coverage, the instant range of less than 10% overlaps the prior art range of at least 5% and is therefore prima facie obvious.

Regarding claims 3-4, Staniforth et al. teach that the formulation comprises from 0.02 to 1.5% by weight of magnesium steatrate in the final formulation (p. 5-6; p. 14, lines 12-17). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, with regard to the surface coverage, the claimed ranges lie within the range taught by the prior art and are therefore prima facie obvious.

Regarding claims 5, 12 and 14, Staniforth et al. teach that the active ingredients are preferably Formoterol and Budesonide (p. 5-6; claim 3).

Regarding claims 6-7 and 22, Staniforth et al. teach that the carrier is alpha-lactose monohydrate (p. 14-15; claim 9).

7. Claims 13, 15-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth et al. (WO 01/78693) (pub. Oct. 25, 2001) (provided by Applicants) as applied to claims 1-7, 12, 14 and 22 above, and further in view of Keller et al. (WO 00/28979) (pub. May 25, 2000) (machine translation)

Regarding claims 13 and 15-21, Staniforth et al. teach each limitation of claims 1 and 5 but fail to teach the specific active ingredients of claims 13 and 15-21. Keller et al. cure this deficiency.

Regarding claims 13 and 15-21, Keller et al. teach a dry powder for inhalation comprising magnesium stearate to improve the moisture resistance of the dry powder (p. 1 and 3). The active ingredient may be formoterol, budesonide, tiotropium, ipratropium, oxitropium, glycopyrronium, andolast, iralukast, pranlukast, imitrodast, seratrodast, zileuton, zafirlukast, montelukast, filaminast, piclamilast, apafant, forapafant, israpafant, amiloride, furosemide, morphine, fentanyl, pentazocine, buprenorphine, pethidine, tilidine, methadone, heroin, sildenafil, alprostadil, phentolamine, or a peptide such as insulin, erythropoietin, gonadotropin or vasopressin (p. 5).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Staniforth et al. with those of Keller et al. to substitute known active agents delivered via a dry powder formulation for formoterol and/or budesonide. One would have been motivated to do so because Keller et al. teach that the active compound in a dry powder formulation comprising magnesium stearate may be chosen from several active compounds, including formoterol and budesonide.

Regarding claim 23, Keller et al. teach that the carrier is in most cases lactose but may also be mannitol (p. 2). It would have been within the purview of a skilled

artisan to substitute mannitol for lactose since Keller et al. teach that either may be used as a carrier material in a dry powder inhalation formulation.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-7 and 12-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10 and 24-42 of copending Application No. 12/536,980 in view of Staniforth et al. WO 01/78693) (pub. Oct. 25, 2001).

Both the instant claims and the copending claims are directed to a dry powder formulation for inhalation comprising active particles and carrier particles for supporting the active particles, the formulation further comprising magnesium stearate wherein the magnesium stearate is disposed on the surface of the carrier particles to provide a

surface coverage of less than 10% on the carrier particles. However, the copending claims claim a multi-dose dry powder inhaler containing the dry powder formulation. Staniforth et al. cure this deficiency.

Staniforth et al. teach a powdery formulation for use in a multidose dry powder inhaler comprising active ingredients, coarse carrier particles and from 0.02 to 1.5% by weight of magnesium steatrate in the final formulation (p. 2, lines 6-9; 5-6; p. 14, lines 12-17; claim 1).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the claims of the instant application with the teachings of Staniforth et al. to use the dry powder formulation in a multi-dose dry powder inhaler. One would have been motivated to do so because Staniforth et al. teach the same formulation as in the instant and copending claims and teach that the formulation may be used in a multi-dose dry powder inhaler.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 8:15 to 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. K./
Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611